

DEC 20 2013

K132329

510(k) Application

Nivatopic™ Plus

510(k) SUMMARY

(in accordance with 21 CFR 807.87(b) and 21 CFR 807.92)

Nivatopic™ Plus

1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Akesis
248 Latitude Lane, Suite 104
Lake Wylie, SC 29710

Phone: (803) 831-7657
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Email: lara.noah@akesis.com

Contact Person: Lara Noah, Associate Director, Global Regulatory Affairs

Date Prepared: July 22, 2013

2. Name of Device and Name/Address of Sponsor

Nivatopic™ Plus

NivaGen Pharmaceuticals, Inc.
3100 Fite Circle #208
Sacramento, CA-95827

Common or Usual Name

Dressing, Wound & Burn, Hydrogel w/drug and/or biologic

Classification Name

Device	Unclassified
Review Panel	General & Plastic Surgery
Product Code	FRO
Unclassified Reason	Pre-Amendment
Submission Type	510(k)

3. Substantial Equivalent Devices:

Nivatopic Plus is substantially equivalent to the currently marketed devices, Hylatopic Plus™ Cream, cleared under 510(K) # K110727, and distributed by PreCision Dermatology,

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Nivatopic™ Plus

Inc. and HPR™ Plus Emollient Foam, cleared under 510(K) # K113774, and distributed by PruGen, IP Holdings Inc.

The safety evaluation meets the requirements as set forth by USP and ISO. The indications of use, device description and performance testing described above and in this 510(K).

4. Device Description:

Nivatopic Plus is a non-sterile, steroid free, semi-viscous emulsion intended for topical application applied 3 times per day or as needed. It is presented as a Prescription (requires a physician diagnosis of disease state) for use.

5. Intended Use Indications for Use:

Nivatopic™ Plus

Rx Use: Nivatopic Plus is indicated to manage and relieve the burning, itching, and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Nivatopic Plus also helps relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

6. Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s):

All products referenced are non-sterile emulsions that are applied topically to relieve the symptoms of various dermatoses.

7. Conclusions:

Functional and performance testing has been conducted to assess the safety and efficacy of Nivatopic™ Plus and the results are satisfactory.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NivaGen Pharmaceuticals Incorporated
% Dr. Loren Gelber
Akesis, LLC
248 Latitude Lane, Suite 104
Lake Wylie, South Carolina 29710

December 20, 2013

Re: K132329
Trade/Device Name: Nivatopic™ Plus
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 10, 2013
Received: October 31, 2013

Dear Dr. Gelber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K132329

Device Name: Nivatopic™ Plus

Indications for Use:

Rx: Nivatopic™ Plus is indicated to manage and relieve the burning, itching, and pain experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. Nivatopic™ Plus also helps relieve dry, waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Prescription Use: <input checked="" type="checkbox"/>	AND/OR	Over-the-Counter Use: <input type="checkbox"/>
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)